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DNI NEVADA INC. 510(k) *SigmaPace 1000 External Pacemaker Analyzer*

1 – 510(k) SUMMARY

2-	**Contact Person:**	Kristine G. Boggs, Quality Assurance Manager 775-883-3400 x265 (phone) 775-883-9541 (fax) boggsk@dninevada.com Establishment Registration Number: 2921581 Establishment will be both manufacturing and marketing SigmaPace 1000 Preparation Date: May 29, 2001
3-	**Classification Name:**	Analyzer, Pacemaker Generator Function, Product, DTC, Class II
	Common Name:	External Pacemaker Analyzer
	Proprietary Name:	SigmaPace 1000

4- Substantially Equivalent To: The device is substantially equivalent to the following two legally marketed predicate devices:

- Netech, Model EXPMT 100 External Pacemaker Tester, #K961582
- Bio-Tek Inc, Model PMA-1 Pacemaker Analyzer, #K903966

SigmaPace 1000 and the predicate External Pacemaker Analyzers have the identical intended use and there are no new technological features or issues that would raise concern of safety or effectiveness.

5 & 6 – Intended Use and Description of Device: This device is intended for use as an external pacemaker analyzer. It is intended to be used by biomedical technicians, third party service organizations, and manufacturers to perform regular preventative maintenance checks on external pacemakers, to verify operations of external pacemakers returned from repair, to assist repair technicians in isolating intermittent performance problems, and as a tool for training medical personnel in the use of external cardiac pacemakers. This device is not to be used as an external cardiac pacemaker calibrator or to make any adjustments based on SigmaPace 1000 test results. This device is not used on patients and does not perform any monitoring, diagnosing, or therapeutic functions.

The SigmaPace 1000 is a device used to verify the performance of various parameters of external cardiac pacemakers. This is done by connecting the external leads of the pacemaker to one of the two channel inputs on the SigmaPace 1000 and selecting the appropriate test either by using the press buttons on the front panel display or via commands sent through the serial port (RS232). The SigmaPace 1000 can perform a variety of Transcutaneous and Transvenous (Atrial and Ventricular) Pacer tests.

- Pulse current, rate width , and energy
- Qualitative demand and async mode tests
- Amplitude sensitivity tests
- Noise immunity tests
- Paced and Sensed Refractory tests
- Selectable model specific transcutaneous algorithms
- Selectable test loads
- DC leakage current (tranvenous)
- Current drain test (transvenous)
- Long term test for pacer output stability
- ECG simulation for training activities

7 – Summary of Technological Characteristics of Device Compared to Predicate:
The SigmaPace 1000 is a dual channel device capable of testing external cardiac pacemakers. The predicate devices have the same intended use and perform most of the same functions as the SigmaPace 1000.
The SigmaPace 1000 is different in that is has dual channel input instead of single channel inputs to allow four pacemaker leads to be tested instead of two. The SigmaPace 1000 also has 5 lead and high level ECG output to allow it to be used with monitors and similar devices for training purposes. DNI has also included a number of manufacturer specific algorithms for improving testing of specific external cardiac pacemaker models. Last, the SigmaPace 1000 has increased test load selections over the predicate devices.

8 – Performance Testing: (Verification and Validation)
This device has undergone and continues to go through a variety of verification and validation testing. Each feature is tested to ensure it meets the requirements as defined in the product specification and advertising. To date, testing has been successfully completed for menu structure, test load selections, battery circuitry, transcutaneous test (ventricular channel), tranvenous tests (both atrial and ventricular channels), internal microprocessor clock frequency, algorithms testing, baud rate, and serial port operation. The data report for the first level validation as well as the full validation plan can be found in the Appendix of this submission.

9- Clinical Testing: Clinical testing was not required since the device is test equipment, and is never in contact with a patient nor do they have any diagnostic, therapeutic, or monitoring patient function. It is not intended to be used for calibrations and should not be used for clinical calls.

10 – Conclusions from testing: The testing conducted to date and that will be conducted prior to release will support all product claims for intended use including accuracy and full feature operation.

11 – Other Information of Interest to the FDA:

Potential System Hazards: The primary system function hazards were determined, reviewed, and addressed. The hazard analysis was aimed at identifying were error could occur which could cause believable but incorrect results. The hazard analysis detail can be found in the Appendix of this submission. In summary, the analysis looked at potential errors with keypad failures, display problems, serial port failures, LED indicator failure, failure of measurement circuitry or stimulus circuitry to be out of tolerance or improperly working, battery failure conditions, including shorts and low or no battery, short circuit of DN input node, and defibrillator discharge into Sigma Pace 1000.

User Safety Consideration: The SigmaPace 1000 is designed to meet IEC 1010 safety standards. The device itself uses an internal lithium battery with a battery charger that meets UL/CSA safety requirements for test equipment. IEC 1010 safety test leads are sent with each unit sold for further user protection.

The above information is certified to be truthful and accurate to the best of my knowledge.

Kristine G. Boggs
Quality Assurance Manager

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2001

Ms. Kristine G. Boggs
Quality Assurance Manager
DNI Nevada, Inc.
2000 Arrowhead Drive
Carson City, Nevada 89706-0403

Re: K011729
Trade Name: SigmaPace 1000 External Pacemaker Analyzer
Regulation Number: 21 CFR 870.3630
Regulatory Class: II (two)
Product Code: 74 DTC
Dated: May 31, 2001
Received: June 4, 2001

Dear Ms. Boggs:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the

Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4645. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
Radiological Health

Enclosure

510(k) Number (if known): K011729

Device Name: **SigmaPace 1000 External Pacemaker Analyzer**

Indications for Use: The *SigmaPace 1000* External Pacemaker Analyzer is intended for use as regular preventative maintenance and quality assurance checks on external cardiac pacemakers utilized in both the pre-hospital and hospital based environments.

The SigmaPace 1000 is limited to preventative maintenance checks for transcutaneous and transvenous types of temporary external cardiac pacemakers. The SigmaPace 1000 will perform a full range of device-specific testing procedures and protocols developed by the external cardiac pacemaker manufacturers. The SigmaPace 1000 will also provide interactive pacemaker simulation capabilities for applications in clinical training and product demonstration.

The SigmaPace 1000 is intended to be used by biomedical technicians, OEM manufacturers, and third party service facilities to perform preventative maintenance and quality assurance checks on external cardiac pacemakers, to verify the operation of devices returned from repair, and to assist repair facilities in the diagnosis of intermittent operations. The device may also be used by training facilities to train medical personnel.

The SigmaPace 1000 is not used on patients and does not perform any diagnostic, therapeutic, or monitoring functions. Additionally, these devices are not used to test any programmable, implantable pacemakers or any related indwelling cardiovascular catheters or lead wires.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K011729

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR Part 801.109)